

4. Under References, References 1-4 have been omitted since the references are no longer relevant due to the revision in the Pediatric Use section of the package insert. The following references have been added to this section as follows:

., DRAFT LABELING

RECOMMENDATION:

Pending concurrence of the reviewing staff, the draft labeling dated December 18, 1998, for NDA 20-898 is recommended for approval.

/S/

Jean Temeck, M.D.
Medical Reviewer
Medical Reviewer

/S/

David Orloff, M.D.
Medical Team Leader
Chemistry Reviewer

/S/

Ron Steigerwalt, Ph.D.
Pharmacology Team Leader

/S/

David Lewis, Ph.D.
Chemistry Reviewer

/S/

Duu-Gong Wu
Chemistry Team Leader

Mike Fossler, Ph.D.
Biopharm. Reviewer

Hae Young Ahn
Biopharm Team Leader

/S/

Steve McCort
Project Manager

Solomon Sobel
Division Director

APPEARS THIS WAY ON ORIGINAL

ORIGINAL

Baxter

ORIG AMENDMENT

December 18, 1998

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation II
Division of Metabolic and Endocrine
Drug Products
Central Document Room 14B-19
5600 Fishers Lane - HFD-510
Rockville, MD 20857-1706

Re: NDA 20-924: Cernevit™-12 IV Multivitamins

Response to December 17, 1998 Labeling Recommendations

-- MINOR AMENDMENT --

Dear Sir or Madam:

Baxter Healthcare Corporation is providing a revised direction insert in response to your December 17, 1998 letter¹. All changes recommended by the Agency have been incorporated into the insert with the following exceptions for the noted sections:

Drug Reactions

In the last sentence of paragraph 1, we have replaced the word "alpha" with the symbol, "α". We have also rearranged the order of drugs known to bind α₁-acid glycoprotein so that disopyramide is listed first. Of the drugs listed, disopyramide is exclusively bound to α₁-acid glycoprotein. The revised order of drugs is "e.g., disopyramide, propranolol, quinidine and prazosin".

*ISO-Convey Comments to firm re
Labeling:*

① Description section -

¹Letter was received via facsimile on December 16, 1998.

REVIEWS COMPLETED	
CSO ACTION:	
<input type="checkbox"/> LETTER	<input type="checkbox"/> N.A. <input type="checkbox"/> MEMO
CSO INITIALS	DATE

Work:
THIS SECTION: pnda 20-924 amend 11
SHOULD BE
TITLED "DRUG
INTERACTIONS"
NOT "DRUG REACTIONS"
replace WFI with
Sterile Water for Injection
3) Under Drug Reactions, second paragraph first sentence
Baxter Confidential
replace "Folic acid has been reported to be unstable" with "Folic acid has been reported to be unstable"
11/1/99
Page 1
12/18/98

Baxter

The following reference to the recommendations of the Nutrition Advisory Group of the Department of Food and Nutrition, American Medical Association, as noted in the revised **Pediatric Use** section has been added:

"Multivitamin preparations for parenteral use a statement by the Nutrition Advisory Group. J. Paren. Enteral. Nutr. 1979; 3(4): 258-62."

An electronic version of the revised direction insert for the Cernevit™-12 IV Multivitamins product is provided on the diskette in **Attachment 1**. The revised direction insert was saved as a Word 97 document and is entitled "dir_ins2.doc". A marked-up, unformatted paper copy of the revised insert is provided in **Attachment 2** and a clean, unformatted paper copy of the revised insert is provided in **Attachment 3**.

Thank you for incorporating this revised labeling into the file.
If you have questions or comments, please contact Ms. Linda Coleman or Tamima Itani, Ph.D. at (847) 270-2577.

Sincerely,

Marcia Marconi (X)

Marcia Marconi
Vice President, Regulatory Affairs
(847) 270-4637
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